

SOP#: RPS-13

Preparation of Continuing Review or Progress Report

Version #: 2.2

Next Review Date: 05/2024

Approved Date: 05/2022

Review Interval Period: Biennial

NCI Clinical Director Signature:

POLICY

NIH IRBs shall conduct CR of human subjects research at intervals appropriate to the degree of risk, but not less than once per year. For research approved by the IRB on or after January 21, 2019, continuing review may no longer be required for certain categories of minimal risk research as determined by the IRB. However, a progress report may be required.

PURPOSE

To identify the actions necessary to submit a protocol continuing review or a progress report.

RESOURCES

- NIH Office of Intramural Research Policies & Guidance [website](#)
 - Policy 204 – *Levels of IRB Review and Criteria for IRB*
 - Policy 205 – *Requirements for IRB Submissions*
 - Policy 801 – *Reporting Research Events*
 - 400 Series – *Regulatory Protections for Vulnerable Populations, as applicable*
 - 500 Series – *FDA Requirements for Human Subjects Research and Data and Safety Monitoring, as applicable*
 - 700 Series – *International Research Requirements, as applicable*
- HRPP [Policy Memo](#): *Implementation of the 2018 Common Rule and Other Policy Changes*

PROCEDURES

STEP 1: Confirm Protocol Expiration Date

Note: To ensure timely continuing review, submit the continuing review or progress report application to the NIH IRB 6 weeks ahead of the study expiration date.

- Locate IRB Expiration Date or the Continuing Review Due Date:
 - From the previous review's outcome letter:
 - Outcome letters are found in the study's regulatory file in the IRB continuing review folder or in iRIS.
- Create or update the Progress Report Form Tracking Tool, found in the CCR PSO share drive. This tracking tool will calculate the data cut-off date, the request to team due date, the response from team due date, and the progress report form due to the IRB date based on the expiration date.

STEP 2: Review Current Key Study Personnel (KSP) and Required Training

- Review the study personnel listed on the KSP Page and Section 3 of the study application.

Note: Check the current status of study personnel in NED.

- Ensure that all study personnel have met the required Human Research Protection Program (HRPP) training requirements.
 - From the Submissions Page:
 - Select the “Study Management” tab
 - Select the “Study Summary/Profile” tab
 - Under the Study Personnel heading - select the “person icon” next to the investigator’s name and review the training history.

Hint: A faster way to check training requirements: generate a report from iRIS. Go to: My Profile: All Departments Reports: Training: “KSP Training – Select Study (CSV).”

Note: If study personnel is/are not in compliance, contact the CCR Director of Office of Education and Compliance.

- Collect a signed COI Certification form from applicable investigators, as required, per SOP RPS-14.
- Once study personnel have been confirmed and training requirements have been met, submit the Deputy Ethics Counselor (DEC) Form for “covered” protocol, if applicable.
 - It is recommended to submit the DEC Clearance Submission Form approximately 45 days before the CR due date.
 - Upload/attach the updated, signed COI Forms to the DEC Form.

Note: Submit the DEC Clearance Submission Form for Minimal Risk studies that are “covered” even though the IRB does not require it. (The DEC form will not be submitted to the IRB.)

- Save the DEC Clearance in the working documents folder.

STEP 3: Update the Study Application in IRIS

- Create a revision to the Study Application in iRIS to review and/or edit as needed.

STEP 4: Request Data for the Continuing Review/Progress Report from the Research Team

- Create a Continuing Review/Progress Report working documents folder with year or year/month.
- Locate the email template and the protocol information request document found in the CCR PSO shared drive to request information from the research team.
 - Review your Progress Report Form Tracking Tool for when to send the request for data, the data cut off dates, and the date the response is due from the PI and designated study team members.

- Based on accrual/recruitment status, select the appropriate email template and attach the corresponding Information Request. Make necessary edits to the email template and protocol information request form, if applicable.
- Request the Cumulative Enrollment Report as part of the request for data to the research team, if needed.

Note: This may not be needed if the protocol status is in data analysis. For studies in PRES, the reports are run directly by the research team. Otherwise, contact the Central Registration Office (CRO).

- Save the Cumulative Inclusion Enrollment Report (CIER) in the working documents folder when received.
- Send email to PI and designated study team members. Include the Data Manager Supervisors on the email (the current supervisors are named on the PSO “CR Information Request” template).

Note: Make sure you enter the due date for return of information on the form and in the email.

- Save all email communications with the study team in the working documents folder under the sub-folder “Correspondence.”

STEP 5: Update the Continuing Review/Progress Report Form in IRIS

- Select the type of Progress Form you are submitting, i.e., Continuing Review or Progress Report (for minimal risk studies that had initial approval on or after January 21, 2019 and no CR is required).
- Enter the data received from the PI/study team.
 - Review the following fields for consistency between the study application and Progress Report forms:

- Protocol Status, revise if requested by research team

Note: PI may change the study status at time of continuing review.

- Completion dates – update in the CR Form and application, as needed, as follows:

- ◆ Study completion date, update if requested by research team or if the study is still open to recruitment and the date is in the past or will pass in the next review cycle.
- ◆ Primary completion date, update if requested by research team or if the study is still open to recruitment and the date is in the past or will pass in the next review cycle.

- Vulnerable or other special populations
- Accrual Ceiling (ensure consistent with protocol)
- Enter the enrollment data received from the CIER.
 - Number of subjects enrolled to cut-off date by study status should match CIER Form.

- If a multi-site study, check which sites have enrolled participants.

Note: The enrollment tables for NIH CC Site, other domestic sites and foreign sites will be entered separately if NIH is responsible for coordinating the clinical trial.

For Continuing Reviews Only:

- Screen failures, withdrawals, lost to follow-up and death related to the study should be consistent with number of subjects enrolled to cut-off date and the protocol progress.
- Check high level summary against reportable events submission forms in iRIS (i.e., the summary should include information about all UPs, deaths, instances of non-compliance, and new information submitted to the IRB on the Reportable Events Submission Form during the reporting period).
- Upload/select required documents, if applicable:
 - Redacted copy of the last signed study consent just prior to the cut-off date (for each type of IRB approved consent/assent), if applicable
 - Confirm that participant identifiers are not visible, but the date of the participant's signature is visible.
 - Confirm that investigator's signature and date signed are visible (as well as witness, if applicable).
 - Note: Study consents only (e.g., not short forms).
 - Outside local IRB CR approved documents for each site, if applicable
 - DEC clearance, if applicable
 - SMC/DSMB/ISM outcome letters, if applicable
 - Recent RSC approvals, if applicable

Hint: Always review what was previously reported in the prior year's progress report form (including stips); compare to this year's report to look for and correct discrepancies.

STEP 6: QC of Continuing Review/Progress Report Form

- Upload all information provided by the research team into the CR/Progress Report.
- Close the form and wait at least a day to come back to it.
- QC your CR/Progress Report: Review the form for consistency and completeness.

STEP 7: Submit in IRIS

- Assign the Progress Report Form for signature as indicated in iRIS.
- Monitor iRIS until the PI has signed off and IRB has received the Progress Report Form.
- The report will go directly to the IRB for pre-review.

STEP 8: Response to Pre-Review Corrections and/or Stipulations

- Create a new subfolder in the Continuing Review/Progress Report working documents folder, for Response to pre-review corrections and/or IRB Stipulations.
- Working with the PI or designated team member, respond to IRB pre-review comments or stipulations.
- Save responses and correspondence in working documents folder.

STEP 9: IRB Approval

- The PI and Study Contacts will be notified of approval through iRIS Notification.
- Create an Approved Documents subfolder (or approval package) and save the following documents from iRIS:
 - IRB outcome letter(s)
 - Progress Report Form
 - Review Response Submission Form(s) as applicable
 - Study Application
- Save the approved documents in the regulatory file.